IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

MEMORANDUM OF LAW IN SUPPORT OF MCKESSON'S MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING ACTIONABLE CONDUCT

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INTRODUCTION

Under Rule 52(c), the Court applies the same standard at the close of Plaintiffs' case as it would at the conclusion of the evidence: it need not draw any inferences in Plaintiffs' favor and may weigh the evidence as it sees fit. McKesson is entitled to judgment under Rule 52(c) because Plaintiffs have not proven actionable conduct on the part of McKesson that was a substantial factor in causing the alleged public nuisance in Cabell/Huntington that Plaintiffs seek to abate.

Excessive Volume Allegations. Plaintiffs' principal theory of harm is that Defendants shipped an excessive number of prescription opioid pills to their retail pharmacy customers in Cabell/Huntington. But the undisputed record evidence shows that is not true of McKesson. McKesson has had no more than a handful of retail pharmacy customers in Cabell/Huntington at any one time, its shipments to these pharmacies were lower than the national and statewide averages that Plaintiffs presented as probative of wrongdoing, and its total market share in Cabell/Huntington is just ***six percent***.

Furthermore, Plaintiffs presented no concrete evidence that any of the orders placed by McKesson's handful of retail pharmacy customers in Cabell/Huntington were problematic or should not have been shipped. Nor is there ***any*** evidence of diversion occurring at any of the small number of pharmacies that McKesson served. Indeed, Plaintiffs' purported diversion expert, James Rafalski, expressly disavowed any opinion that "diversion occurred at the pharmacy level" for ***any McKesson pharmacy customer*** in Cabell/Huntington. Absent evidence of diversion on the part of a McKesson pharmacy customer, it is impossible for Plaintiffs to show that McKesson's distributions caused any harm in Cabell/Huntington.

Suspicious Order Monitoring Allegations. Plaintiffs also allege that McKesson's suspicious order monitoring ("SOM") systems were deficient. But the record evidence shows that McKesson's systems for preventing diversion at all times complied with DEA's evolving

expectations for the wholesale distribution industry. And, more fundamentally, there is no evidence that any purported failure in McKesson's SOM systems caused any harm in Cabell/Huntington.

1. Plaintiffs' main criticisms of McKesson's pre-2008 system are that McKesson (i) submitted "excessive purchase reports" to DEA to comply with 21 C.F.R. § 1301.74(b)'s suspicious order reporting provisions and (ii) shipped the orders that it identified and reported to DEA as suspicious. But the undisputed record evidence shows that this was standard industry practice—done with the full knowledge and acceptance of DEA—during this time-period. Furthermore, the record is clear that—both before and after 2008—McKesson never shipped any orders that it believed were in danger of being diverted.

2. In response to changing DEA guidance, McKesson introduced a new SOM system in 2008. Under this system, McKesson ***blocked and did not ship any orders*** that exceeded customer-specific thresholds. Notably, no Plaintiff witness ever opined that McKesson failed to set these thresholds in an appropriate manner. Thus, the record is clear that—at all times since 2008—McKesson has blocked all potentially suspicious orders it received. The record is likewise clear that, before approving any requests to increase these customer-specific thresholds, McKesson conducted due diligence to ensure that an increase was warranted.

Plaintiffs only concrete criticism of McKesson's systems during the 2008-13 period is that McKesson failed to report certain allegedly suspicious orders. But there is no evidence that McKesson failed to report any suspicious orders placed by McKesson's handful of retail pharmacy customers in Cabell/Huntington. More fundamentally, the undisputed evidence establishes that—throughout the entirety of this period—McKesson blocked and did not ship any suspicious orders that it identified. And, as Plaintiffs' witnesses admit, an order that is not shipped cannot possibly

be diverted or cause any harm. *See, e.g.,* 5/26 Tr. at 208:10–12 (Mr. Rafalski agreeing that "not reporting the suspicious order to the DEA is not what causes diversion"). Accordingly, any failure on McKesson's part to report suspicious orders to DEA could not have led to diversion in Cabell/Huntington and cannot provide a basis for liability on the part of McKesson.

In any event, the FDA-approved medicines that McKesson shipped to its DEA-registered pharmacy customers would have sat on a shelf, causing harm to no one, unless and until a doctor wrote a prescription and a pharmacist filled it. Moreover, the only form of diversion in Cabell/Huntington that the evidence supports is "medicine cabinet" diversion. This form of diversion occurs ***after*** McKesson delivers prescription opioid medicines to retail pharmacies and those pharmacies dispense the medicines to patients—such as when the patient unlawfully sells or gives away the medicines to a family member or friend. As both common sense suggests and Plaintiffs' own experts confirm, McKesson does not have the ability to prevent and is not a cause of any harm flowing from such medicine cabinet diversion.

3. Finally, the record reflects that, beginning in 2013, McKesson made significant enhancements to its SOM systems, including increased reporting of suspicious orders. Tellingly, Plaintiffs did not even attempt to establish any deficiency in McKesson's systems since 2013. Especially here, where Plaintiffs have waived any claim for past damages and seek only the abatement of a present-day nuisance in Cabell/Huntington, Plaintiffs' complete inability to identify any allegedly actionable conduct in the past eight years is fatal.

LEGAL STANDARDS

A. Rule 52(c)

In a nonjury trial, judgment is warranted when "a party has been fully heard on an issue" necessary to maintain its claim or defense and "the court finds against the party on that issue." Fed. R. Civ. P. 52(c); *see also, e.g.*, *Carter v. Ball*, 33 F.3d 450, 457 (4th Cir. 1994) ("A district

court sitting without a jury may enter judgment as a matter of law against a party on any claim once the party has had a full opportunity to present evidence on that claim."); *First Va. Banks, Inc. v. BP Expl. & Oil Inc.*, 206 F.3d 404, 407 (4th Cir. 2000) (Rule 52(c) "authorizes the court to enter judgment at any time that it can appropriately make a dispositive finding of fact on the evidence").

"In deciding whether to enter judgment on partial findings under Rule 52(c), the district court is not required to draw any inferences in favor of the non-moving party; rather, the district court may make findings in accordance with its own view of the evidence." *Ritchie v. United States*, 451 F.3d 1019, 1023 (9th Cir. 2006). "The court's task is to weigh the evidence, resolve any conflicts in it, and decide for itself in which party's favor the preponderance of the evidence lies." Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure, § 2573.1 (3d ed. 2020); *see also EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 272 (3d Cir. 2010) (under Rule 52(c), "the district court applies the same standard of proof and weighs the evidence as it would at the conclusion of the trial"); *M & M Poultry, Inc. v. Pilgrim's Pride Corp.*, 281 F. Supp. 3d 610, 620 (N.D. W. Va. 2017) ("Rule 52(c) expressly authorizes district judges to resolve disputed issues of fact."); *W.L. Gore & Assocs., Inc. v. Medtronic, Inc.*, 874 F. Supp. 2d 526, 540 (E.D. Va. 2012), *aff'd*, 530 F. App'x 939 (Fed. Cir. 2013) ("To grant JMOL under Rule 52(c), a district judge must weigh the evidence and resolve credibility.").

B. Actionable Conduct

To hold a defendant liable in tort, a plaintiff must prove wrongdoing on the part of that defendant. This fundamental proposition applies with full force to public nuisance claims. *See, e.g.*, *Sharon Steel Corp. v. City of Fairmont*, 175 W.Va. 479, 483, 334 S.E.2d 616, 620 (1985) ("A public nuisance is an act or condition that ***unlawfully*** operates to hurt or inconvenience an indefinite number of persons." (emphasis added)).

Plaintiffs admit that they need to prove that Defendants engaged in "actionable" conduct. 5/3 Tr. at 22:1–5 (opening statement); *see also W. Va. Transp. Co. v. Standard Oil Co.*, 40 S.E. 591, 593 (W. Va. 1901) ("[T]he mere operation by lawful means of lawful business … is not actionable."). And they have at various times suggested that they may satisfy that burden by proving that Defendants' conducted was "unreasonable" or "unlawful." *See, e.g.*, Dkt. No. 1294, at 2 ("Plaintiffs acknowledge that they have to prove the unreasonableness of the alleged conduct…."); 2/9 Pre-Trial Hrg. Tr. at 44:23–24 (Plaintiffs' counsel stating that "in West Virginia, unlawful conduct is a predicate for nuisance").[1] This Court, moreover, denied Defendants' motion for summary judgment on "fault" because, the Court concluded, Defendants failed to prove the absence of a genuine dispute of material fact regarding "the ***reasonableness*** of [their] conduct." Dkt. No. 1294, at 6. Accordingly, for purposes of this brief, McKesson assumes *arguendo* that the standard for "actionable" conduct is unlawful or otherwise unreasonable conduct, and demonstrates that Plaintiffs have failed to prove any actionable conduct on the part of McKesson. McKesson further demonstrates that its allegedly actionable conduct was not a "substantial factor" in producing the purported public nuisance in Cabell/Huntington—which is a fundamental legal premise of Plaintiffs' claim. *See, e.g.*, Dkt. No. 1080.[2]

[1] For the reasons explained in Defendants' Motion for Summary Judgment Regarding Fault, Dkt. No. 1007-3 (Mem. of Law), McKesson respectfully disagrees that Plaintiffs may prevail merely by establishing that Defendants' conduct was unreasonable or ran afoul of alleged regulatory obligations.

[2] McKesson does not agree that the "public nuisance" at issue can be the "opioid epidemic" or "crisis." As explained in Defendants' Memorandum of Law in Support of Motion for Judgment On Partial Findings Regarding Abatement ("Defendants' Abatement Motion"), filed contemporaneously herewith, a public nuisance consists of *conduct* that injuriously affects the public health or safety. *See* Defs.' Abatement Mot. at Part I.B. Thus, Plaintiffs' framing of the nuisance in terms of the alleged downstream effects of Defendants' purportedly wrongful conduct is incorrect, but McKesson assumes it to be true for purposes of this motion.

ARGUMENT

In order to recover an abatement remedy from McKesson, Plaintiffs must show (1) an ongoing public nuisance, (2) actionable conduct by McKesson, and (3) that McKesson's actionable conduct was a proximate cause of the on-going public nuisance.[3] For the reasons explained below, Plaintiffs have not come forward with sufficient evidence of actionable conduct by McKesson that was a substantial factor in creating the present-day opioid abuse problem in Cabell/Huntington.

I. THE EVIDENCE REGARDING MCKESSON'S OPIOID SHIPMENTS INTO CABELL/HUNTINGTON DOES NOT ESTABLISH ACTIONABLE CONDUCT THAT CAUSED HARM IN CABELL/HUNTINGTON.

The gravamen of Plaintiffs' case is that Defendants shipped an excessive volume of prescription opioid medicines into Cabell/Huntington. *See, e.g.*, 5/3 Tr. at 12:25-13:3 (opening statement) (the first "pillar" of Plaintiffs' case is "volume": "We will introduce in painstaking detail the volume of pills that were sold by The Big Three into Huntington-Cabell County."); Third Amend. Compl. ¶¶ 801–03, 805, 823, 862 (alleging "excessive distribution[s]"). But for three reasons, Plaintiffs' evidence does nothing to establish any actionable conduct on the part of McKesson that caused harm in Cabell/Huntington. First, McKesson's total volume numbers are and have been very low in both relative and absolute terms, and any increase in the total volume of McKesson's distributions over time was due to increased good-faith prescribing—not any actionable conduct by McKesson. Second, Plaintiffs failed to prove that McKesson's shipments to its small number of retail pharmacy customers in Cabell/Huntington were improper. And, third,

[3] As discussed in Defendants' Memorandum of Law in Support of Motion for Judgment on Partial Findings Regarding Proximate Causation ("Defendants' Proximate Causation Motion"), filed contemporaneously herewith, Plaintiffs have failed to prove that there is an ongoing nuisance relating to prescription opioid abuse in Cabell/Huntington and have failed to prove that Defendants are a proximate cause of opioid abuse in Cabell/Huntington. *See* Defs.' Proximate Causation Mot. at 9–11; *see also infra* Part II.

Plaintiffs failed to present any evidence that those shipments led to diversion in Cabell/Huntington or were a substantial factor in bringing about the alleged public nuisance.

A. McKesson's Shipments into Cabell/Huntington Were Too Small To Be A Substantial Factor in Cabell/Huntington's Opioid Abuse Problem.

Setting aside McKesson's distributions to the federal government (as Plaintiffs admit is appropriate), the record shows that McKesson's shipments of opioid medicines into Cabell/Huntington were too small to be a substantial factor in their opioid abuse problem.

By a significant measure, McKesson's largest customer in Cabell/Huntington is the Veterans Affairs Medical Center ("V.A. Medical Center"). Indeed, of McKesson's total shipments into Cabell/Huntington, ***over 76% were made*** pursuant to McKesson's contract to provide nationwide pharmaceutical distribution services ***to the federal Department of Veterans Affairs***. 5/11 Tr. (McCann) at 168:10–16 ("76.1% of McKesson's total distribution into Huntington and Cabell … [of] oxycodone and hydrocodone" went to the V.A. Medical Center).

Plaintiffs presented ***no evidence*** challenging McKesson's shipments to V.A. facilities. Rather, as Mr. Rafalski conceded, he did not consider shipments to the V.A. because they were not "***applicable to the diversion topic***."[4] 5/26 Tr. at 271:24–272:6 (emphasis added); *see also* 5/11 Tr. at 166:24–167:14 (Dr. McCann's analyses were focused exclusively on "retail and chain pharmacies"); 5/12 Tr. at 15:2–7 (Dr. McCann did "not include[e] the roughly 80 percent of the shipments [by McKesson] that came to the V.A.").

McKesson's share of the Cabell/Huntington retail pharmacy market is tiny. Indeed, Dr. McCann admitted that "McKesson's share of oxycodone and hydrocodone to Cabell County and

[4] McKesson maintains the position stated in its Motion for Dismissal on Derivative Sovereign Immunity Grounds that liability may not be imposed on McKesson based on those shipments. *See* Dkt. No. 1013 (Mem. of Law). But the Court need not even reach that issue, because Plaintiffs have waived any challenge to McKesson's V.A. shipments.

Huntington if you remove the V.A. from the total shipments and from McKesson's shipments" was just "***6 percent***." 5/11 Tr. at 182:8–20 (emphasis added). Dr. McCann further admitted that this made McKesson ***sixth in market share*** among wholesale distributors for oxycodone and hydrocodone shipments into Cabell/Huntington. *See id.* at 180:20–25 ("Q…. [T]here are … five companies that shipped more oxycodone and hydrocodone to Huntington and Cabell than McKesson, excluding the V.A.; correct? A. Correct.").

Similarly, Dr. McCann presented various charts comparing Defendants' shipments into Cabell/Huntington with statewide and national averages—which Plaintiffs suggested were probative of Defendants' wrongdoing. *See, e.g.*, Trial Ex. P-44711 (chart of per capita distribution for the United States, West Virginia, and Cabell/Huntington). These charts, however, demonstrate that McKesson's shipments into Cabell/Huntington were ***substantially lower*** than the corresponding statewide and national averages. *Id.* at 25 (McKesson's per capita distribution rates). For example, Dr. McCann confirmed that McKesson's per capita distribution to Cabell/Huntington pharmacies was "45 percent lower" than its West Virginia per capita rate and "15 percent lower" than its national per capita rate. 5/11 Tr. at 176:25–177:19.

To the extent the aggregate volume of McKesson's opioid distribution increased in the late 1990s and early 2000s, moreover, the undisputed evidence shows that increase was caused ***not*** by any actionable conduct on the part of McKesson, but rather by a change in the standard of care for treating pain that led to significantly increased levels of good-faith opioid prescribing. *See* Proximate Causation Mot. at Part I.A. Put simply, McKesson's increased opioid distribution merely ***reflected*** the across-the-board increased prescribing seen during the late 1990s and 2000s—McKesson's conduct did not cause (and could not have caused) that increase.

Plaintiffs' core legal theory is that "Defendants' conduct and the resulting over-supply of opioids was a substantial factor in producing the public nuisance in [Cabell/Huntington]." Dkt. No. 1080, at 12; *see also id.* at 5 & n.6 (assertion by Plaintiffs that they may prevail if they prove that a Defendant's wrongdoing was "a 'substantial factor' in causing the[ir] harm"). Here, the facts that (i) McKesson only serviced a handful of pharmacy customers in Cabell/Huntington at any one time, (ii) its shipments account for only six percent of challenged opioid distribution in Cabell/Huntington—even disregarding the established role that other actors such as manufacturers, doctors, and patients play in driving demand for the medicines that Defendants shipped—preclude any finding that McKesson was a "substantial factor" in producing the alleged public nuisance in Cabell/Huntington.

B. Plaintiffs Have Not Proven Any Wrongful Shipments by McKesson into Cabell/Huntington.

Plaintiffs allege that McKesson failed to maintain effective controls against diversion, and suggest that this alleged failure resulted in improper shipments to McKesson's pharmacy customers in Cabell/Huntington. But the trial evidence does not support that suggestion.

McKesson "[c]urrently" has only "three [pharmacy] customers" in Cabell/Huntington. 5/25 Tr. (Ashworth) at 197:25–198:3. While specific customers have changed over time, McKesson has serviced a similarly small number of customers since as far back as 2010. *Id.* at 198:4–6 (testifying that he had "[p]robably a couple, two or three" pharmacy customers in Cabell/Huntington in 2010).

The record is devoid of evidence that McKesson improperly shipped prescription opioids to any of these small handful of pharmacy customers in Cabell/Huntington. In fact, Plaintiffs solicited ***no testimony*** whatsoever about a number of these customers. Instead, Plaintiffs' evidence consists of only a bare recitation of McKesson's shipment volumes:

- ***Medicine Shoppe Pharmacy.*** Plaintiffs presented evidence that from 2006 through 2014, McKesson shipped 1,500 dosage units of hydrocodone to Medicine Shoppe Pharmacy. *See* Trial Ex. P-44755 at 6. Plaintiffs' expert, Dr. Craig McCann, described this volume as "essentially zero." 5/10 Tr. (McCann) at 183:15–20. There was no evidence of any McKesson wrongdoing with respect to the Medicine Shoppe Pharmacy and no evidence of any diversion occurring at this pharmacy.

- ***Fruth Pharmacy Locations (Fruth #2, #5, #12).*** Plaintiffs presented evidence that over an eight-year period, McKesson distributed a combined 45,700 dosage units of hydrocodone to three Fruth pharmacies. *See* Trial Ex. P-44752 at 6, 11–12. This amounts to an average of less than 6,000 dosage units a year (476 dosage units a month). There was no evidence of any McKesson wrongdoing with respect to these Fruth Pharmacies and no evidence of any diversion occurring at these pharmacies.

- ***McCloud Family Pharmacy.*** Plaintiffs presented a data summary under Rule 1006 that indicates that, from 2015 to 2016, McKesson distributed 195,980 dosage units of hydrocodone and 126,500 dosage units of oxycodone to this pharmacy. *See* Trial Ex. P-44754 at 39. There was no evidence of any McKesson wrongdoing with respect to the McCloud Family Pharmacy and no evidence of any diversion occurring at this pharmacy.

Plaintiffs only even attempted half-hearted critiques of two of McKesson's pharmacy customers: (1) Custom Script Pharmacy and (2) Rite Aid. But these critiques were unsupported by any evidence of wrongdoing or diversion:

Custom Script. McKesson's Retail Sales Manager, Tim Ashworth, testified that Custom Script was a McKesson customer from "2010 to 2013," and that the store has not done business with McKesson in the last eight years. 5/25 Tr. (Ashworth) at 234:3–6. While Custom Script's sales data illustrates that its ratio of controlled substance purchases to non-controlled purchases from McKesson was higher than average, Mr. Ashworth explained that Custom Script "specialize[d] in compounding specific medications that aren't available in the marketplace from a distributor like McKesson." *Id.* at 234:7–13, 235:11–20. Custom Script purchased the majority of its non-controlled substance compounding materials from another distributor, and its controlled substances from McKesson, which "skew[ed] the number" of their controlled substance to non-controlled purchases from McKesson. *Id.* at 234:22–235:20; *see also* 5/25 Tr. at 143:15–21 (Mr.

Oriente would "tak[e] into consideration" factors such as if the store "served customers like [h]ospices," or was a "specialty compounding pharmac[y]" in assessing a customer's controlled to non-controlled purchase ratio).

Mr. Ashworth explained that Custom Script's controlled substance ordering increased in 2010 due to the pharmacy servicing "Cabell-Huntington Hospital's oncology clinic," the "Hospice of Huntington," and "a pain management clinic." 5/25 Tr. (Ashworth) at 237:18–238:23. By 2013, however, diligence file materials show that the pharmacy dispensed 2,000 dosage units or less of hydrocodone and oxycodone per month—"a low number." *Id.* at 245:1–20; *see also* Trial Ex. P-13284 at 9 (Custom Script diligence documents). Plaintiffs' expert, Dr. McCann, acknowledged that Custom Script's overall distribution was "in the bottom half of pharmacies by volume in Huntington/Cabell." 5/11 Tr. at 185:19–25.

In short, there is no record evidence that would support a finding that McKesson's limited distribution to this single pharmacy, ending eight years ago, caused any historical harm—and certainly any present-day opioid abuse problems in Cabell/Huntington.

Rite Aid. McKesson also serviced four Rite-Aid pharmacies in Cabell/Huntington. *See* Trial Ex. P-44757 at 6–7; 5/11 Tr. (McCann) at 196:8–15 (Dr. McCann's Rite Aid shipments considered "four pharmacies combined"). As Dr. McCann explained, like many chain pharmacies Rite Aid engaged in "self-distribution," meaning that "they [got] some of the[ir] prescription opioids from traditional distributors like McKesson, but they also get some prescription opioids directly from the manufacturer they distribute to themselves." 5/11 Tr. at 196:15–22; *see also* 145:15–146:12 (Mr. Oriente testifying that Rite Aid typically "self-distributed" hydrocodone).[5]

[5] In light of Rite Aid's centralized corporate structure, which included its own internal regulatory affairs team, Michael Oriente explained that McKesson worked "with their corporate office on any [due diligence] reviews and not with the individual pharmacy." 5/25 Tr. at 106:20–23. This

Consistent with Rite Aid's self-distribution model, Dr. McCann's analysis confirms that for all dosage units of oxycodone and hydrocodone shipped to Rite Aid pharmacies in Cabell/Huntington, "***63% of that was distributed by Rite Aid*** and 37% by McKesson." 5/11 Tr. (McCann) at 21:8–21 (emphasis added). Notably, Mr. Rafalski admitted that he could not opine as to "whether Rite-Aid helped cause the opioid crisis in Huntington and Cabell County." 5/27 Tr. at 27:14–28:11.[6] If Plaintiffs' own expert cannot opine that Rite-Aid itself helped cause the opioid crisis in Cabell/Huntington, then he necessarily cannot opine that McKesson's minority fraction of shipments to Rite-Aid helped cause the opioid crisis.[7]

Moreover, the West Virginia Board of Pharmacy regularly inspected the Rite Aid stores in Cabell/Huntington and did not identify concerns with these pharmacies. Indeed, in one case, the board remarked that the Rite Aid location it reviewed was a "GOOD PHARMACY!" for which "all prescriptions appear prescribed for a ***legitimate medical use***." Trial Ex. DEF-WV-01989 at 19–20 (emphasis added).

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coordination with Rite Aid reflected the fact that Rite Aid's corporate office had "their own Regulatory Department," had "documented policies and procedures on the filling of controlled substances," and would "conduct … due diligence" of Rite Aid stores in addition to McKesson's review. *Id.* at 141:4–24. Mr. Oriente testified that when McKesson "told the DEA that [it was] taking a different approach for the retail national chains than … for the independent pharmacies" the DEA "did not" express disagreement. *Id.* at 107:6–9.

[6] In forming his opinions in this matter, Mr. Rafalski did not review any of the Board of Pharmacy inspection reports containing this sort of pharmacy-specific information. *See* 5/27 Tr. (Rafalski) at 26:18–20 (Q…. You haven't done that review? A. I have not, not for the West Virginia Board of Pharmacy, sir.").

[7] In addition to distributing only about 1/3 of Rite Aid's total volume, after McKesson took over hydrocodone distribution for Rite Aid in 2014 when hydrocodone became a Schedule II drug, Dr. McCann testified that "[t]he shipments [of hydrocodone made by McKesson] appear to have declined by approximately half" as compared to Rite Aid's self-distribution total. 5/11 Tr. at 198:23–199:2.

In short, Plaintiffs have not established any actionable conduct by McKesson in connection with its role as secondary distributor to a handful of Rite Aid stores in Cabell/Huntington.

C. Plaintiffs Failed To Present Any Evidence that McKesson's Shipments to Pharmacies in Cabell/Huntington Led to Diversion.

Whether for Custom Script, Rite Aid, or otherwise, Plaintiffs have not introduced ***any evidence*** of diversion occurring at any of the pharmacies serviced by McKesson in Cabell/Huntington. This failure alone entitles McKesson to judgment under Rule 52(c).

Despite putting on over six weeks of testimony, only two Plaintiff witnesses even purported to offer testimony regarding any wrongdoing by McKesson.[8] But the first, Mr. Rannazzisi, testified that he "ha[d] not reviewed any documents related to West Virginia" and therefore could not identify "any orders in Huntington or Cabell County that [he] believed … should have been blocked by [McKesson] but were not." 6/9 Tr. (Rannazzisi) at 14:6–17. According to Mr. Rannazzisi, moreover, Defendants had an obligation to block orders that were likely to be "diverted … somewhere down the road." 6/7 Tr. at 216:13–18. Thus, his inability to identify

[8] While Jakki Mohr testified that McKesson engaged in "marketing," she further testified that "there's nothing improper" about marketing, 6/11 Tr. (Mohr) at 112:19–21, 124:7–10, and declined to opine that any McKesson marketing was "false or misleading," much less "unlawful," *id.* at 97:3–5, 123:22–124:6. Similarly, Lacey Keller testified that McKesson could have purchased commercially available data to identify "high volume" prescribers, but disavowed offering an opinion that "any of those prescribers were prescribing too much opioid medication," *see* 6/15 Tr. (Keller) at 169:9–15, or that McKesson should have done anything with the data she described, *see id.* at 250:25–251:5 ("Q. Can you identify specific actions that distributors should take based on a specific level of filling of prescriptions from the [high prescribers] at their pharmacy customers? A. I don't offer an opinion on what distributors should do with that data."); *see also* 6/9 Tr. at 112:16–113:5 (Mr. Rannazzisi testifying that the DEA "do[esn't] investigate based on quantities" prescribed); *id.* at 115:15–23 (Mr. Rannazzisi agreeing that it was "a very true statement" that "'the amount of dosage units per prescription will never be a basis for investigation for the overwhelming majority of physicians.'"); 5/26 Tr. at 117:8–12 (James Rafalski agreeing that "[t]he DEA does not expect distributors to second-guess the legitimate medical judgments of prescribers").

orders that McKesson should have blocked is tantamount to an admission that he could not identify any orders that were likely to be diverted.

Mr. Rannazzisi further admitted that he could ***not*** identify:

- Any occasion "where [he] or someone at DEA told … [McKesson] that [it] should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy." 6/9 Tr. (Rannazzisi) at 99:10–16.

- Any instance where McKesson "supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA." *Id.* at 151:19–23.

- Any instance where McKesson "supplied prescription opioids to a DEA licensed pharmacy in Huntington or Cabell that the DEA had warned the distributor not to supply." *Id.* at 151:24–152:3.

Accordingly, Mr. Rannazzissi's testimony does nothing to establish that McKesson ever made an improper shipment into Cabell/Huntington that was diverted to illicit use.

Nor would the testimony of Plaintiffs' purported diversion expert, Mr. Rafalski, establish that McKesson's conduct caused a public nuisance in Cabell/Huntington—even if admitted, which it should not be. *See* Mem. of Law in Support of Defs.' Renewed *Daubert* Mot. to Exclude the Opinions of James E. Rafalski (Dkt. No. 1386).[9]

Mr. Rafalski admitted that he has no opinion that "diversion occurred at a pharmacy level" for ***any pharmacy*** in Cabell/Huntington, including Custom Script and the four Rite Aid locations serviced by McKesson. 5/26 Tr. (Rafalski) at 135:8–13. This concession alone is fatal to Plaintiffs' case—absent concrete evidence of any diversion occurring at a pharmacy serviced by

[9] Should the Court grants Defendants' motion to exclude Mr. Rafalski's testimony, that would provide an independent basis for granting judgment under Rule 52(c). As described herein, the vast majority of Plaintiffs' "actionable conduct" (and causation) evidence (such as it is) comes from Mr. Rafalski's flagging testimony and his *ipse dixit* opinions regarding Defendants' programs.

McKesson, Plaintiffs could not possibly prove that McKesson was a substantial factor in bringing about the opioid abuse problem in Cabell/Huntington.

Mr. Rafalski further admitted that he is:

- Not "aware of any pills that were shipped by McKesson … that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription." 5/26 Tr. at 131:6–10.
- Not "aware of … McKesson ever supplying a pharmacy that was not licensed by the DEA." *Id.* at 131:21–23.
- Not "aware of any prescription in this case relating to [McKesson] … that was dispensed without a pharmacist present with that pharmacist" exercising his or her "corresponding responsibility." *Id.* at 132:24–133:4.

In addition, Mr. Rafalski testified that, to the extent any diversion occurred ***after*** the medicines that McKesson delivered to pharmacies in Cabell/Huntington were dispensed to patients, McKesson is not responsible for that diversion. 5/26 Tr. at 196:7–11 (agreeing that "when a patient misuses medication that was prescribed for a legitimate medical use, whether it's giving it away or selling it, the patient is responsible for that"); *id.* at 198:19–23 (agreeing that "when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point"). Accordingly, the testimony of Mr. Rafalski is plainly insufficient to establish that McKesson caused diversion—or any downstream harms flowing from diversion—in Cabell/Huntington.

II. THE EVIDENCE REGARDING MCKESSON'S SOM SYSTEMS DOES NOT ESTABLISH ACTIONABLE CONDUCT THAT CAUSED HARM IN CABELL/HUNTINGTON.

Plaintiffs have asserted that McKesson's suspicious order monitoring programs were deficient, and that those deficiencies led to diversion in Cabell/Huntington, but the weight of the record evidence conclusively undermines both assertions.

The Court heard evidence regarding three main iterations of McKesson's SOM programs, which are discussed in turn below. The clear weight of the record evidence shows that these programs were designed and implemented consistent with DEA's contemporaneous guidance and expectations for the wholesale distribution industry. And there is ***no evidence*** that McKesson's alleged SOM deficiencies actually led to any diversion or harm in Cabell/Huntington.

A. McKesson's Pre-2008 System Complied with Contemporaneous DEA Guidance and Prevailing Industry Standards.

The record evidence does not support Plaintiffs' assertion that McKesson's pre-2008 system was unreasonable or failed to maintain effective controls against diversion in light of DEA guidance and standard industry practice during the pre-2008 period. *See, e.g.*, *Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 336 (4th Cir. 1991) ("While conformity with industry practice is not conclusive … the cases where a member of industry will be held liable for failing to do what no one in his position has ever done before will be infrequent.").[10] Nor is there any evidence that McKesson's alleged SOM failures—occurring well over a decade ago—were a substantial factor in bringing about Cabell/Huntington's present-day, ***illegal*** opioid problem.[11]

Prior to 2008, McKesson operated a SOM program that was set out in Section 55 of McKesson's Drug Operations Manual ("Section 55"). *See* Trial Ex. MC-WV-00451. Under

[10] S*ee also Stonehocker v. Gen. Motors Corp.*, 587 F.2d 151, 157 (4th Cir. 1978) ("It is general law that custom is admissible against which a finder of fact may measure a standard of care …."); *Workman v. Wal-Mart Stores East, L.P.*, 2007 WL 5415489, at *4 (S.D. W. Va. Aug. 27, 2007) ("Custom and common practice of an industry or trade may be useful in determining whether a duty of care has been met." (citing *Bates v. Sirk*, 230 S.E.2d 738, 741 (W. Va. 1976)).

[11] As explained in Defendants' Proximate Causation Motion, filed contemporaneously herewith, Cabell/Huntington no longer has a significant prescription opioid abuse problem. Rather, to the extent that those communities continue to have an opioid abuse problem, the problem consists of illegal, non-prescription opioid abuse. And this has been the case since at least 2013. *See* Defs.' Proximate Causation Mot. at 9–11.

Section 55, each McKesson distribution center submitted daily and monthly faxes to DEA, called "DU-45" reports, which "listed all suspicious orders identified from [its] customers' purchasing patterns."[12] The submission of DU-45 reports was in addition to McKesson's "constant" reporting of all prescription opioid distributions to DEA's Automated Reporting of Controlled Substances ("ARCOS") database, which McKesson has done since the advent of the ARCOS system. 5/25 Tr. at 35:17–36:15 (Mr. Oriente testifying that McKesson's ARCOS reporting was "constant" since before 2008 through present day).

Suspicious Order Reporting. Plaintiffs complain that McKesson during this period submitted "excessive purchase" reports to DEA to comply with the "suspicious order" reporting provisions of 21 C.F.R. § 1301.74(b). But the record evidence shows that this was a common industry practice at the time, and was done with the full knowledge and approval of DEA.

McKesson's DU-45 reports included text expressly informing the DEA that the submission was made "[p]ursuant to CFR 21 [§] 1301.74(B)" and "reflect[ed] purchases from customers for Schedules II-V controlled substances which exceed the monthly average" used by McKesson to identify potentially suspicious orders. *See, e.g.*, Trial Ex. P-42747 at 2; Trial Ex. MC-WV-02143 at 2. The record is clear that, prior to 2008, DEA accepted such excessive purchases reports from McKesson and other wholesale distributors as compliant with 21 C.F.R. § 1301.74(b). For example, former DEA official Thomas Prevoznik—whose deposition testimony Plaintiffs designated for use at trial—testified:

> Q. We've already established that prior to 2007 you're not aware of the DEA saying, no more excessive purchase reports, right?
>
> A. Right. Correct.

[12] 5/25 Tr. (Oriente) at 42:17–25; Trial Ex. P-42747 (example monthly DU-45 report); MC-WV-02143 (example daily DU-45 reports).

> ….
>
> Q. And the DEA was aware that there were, in fact, being routinely submitted by distributors excessive purchase reports on a regular basis, right?
>
> A. We were aware.

Dep. Tr. (Prevoznik) at 126:18–22, 127:7–12; *see also infra* nn.21 & 22. It is undisputed, moreover, that McKesson has ***always*** "manual[ly] block[ed]" shipment of ***all*** orders that the company "believed [were] likely to be diverted." 5/25 Tr. at 48:4–10; *see also* MC-WV-00451 at 51 (Section 55 Manual stating that "order fillers … are expected to report to management any unusual purchase request before orders are filled" so that a supervisor can determine whether to block or fill). Accordingly, there is no record evidence that McKesson's reporting practices during the pre-2008 period constituted actionable conduct.[13]

Shipment of "Suspicious Orders." Plaintiffs also complain that McKesson shipped the orders that it identified and reported to DEA as suspicious during the pre-2008 period. Here again, however, the overwhelming weight of the record evidence is that DEA did not expect distributors to block suspicious orders during this time period and, as a result, the wholesale distribution industry as a whole did not do so.

As an initial matter, Plaintiffs' critique ignores the clear testimony from McKesson that its SOM systems ***at all times*** required that orders the company "believed [were] likely to be diverted" be "manual[ly] block[ed]." 5/25 Tr. (Oriente) at 48:4–10. In addition, Plaintiffs' own expert acknowledged that he could not identify "any distributor … that blocked every order it reported to the DEA" prior to 2006. 5/26 Tr. (Rafalski) at 269:14–20. The timeline of this policy shift has

[13] Moreover, as explained below, there is no evidence that any purported reporting failure by McKesson caused any diversion or harm in Cabell/Huntington. *See infra* at 36. Accordingly, any such reporting failures would not be relevant to the question whether McKesson caused the alleged public nuisance.

been recognized by the D.C. Circuit Court of Appeals, which noted that "DEA ***first articulated*** that [do not ship] requirement in *Southwood*," which was a 2007 administrative decision. *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 222 (D.C. Cir. 2017) (emphasis added); Trial Ex. P-23736 (72 Fed. Reg. at 36,501). Accordingly, McKesson's practice of shipping the potentially suspicious orders it identified was entirely consistent with contemporaneous DEA guidance and standard industry practice during the relevant pre-2008 time-period. *See supra* n.10 and accompanying text.[14]

Moreover, the record evidence undercuts any assertion that shipping orders that met the regulatory definition of "suspicious"—but that lack any indicia of diversion—caused diversion or harm in Cabell/Huntington or elsewhere. The vast majority of orders meeting the regulatory definition of a "suspicious order" (*e.g.*, orders of "unusual size") are not problematic or likely to be diverted. 5/26 (Rafalski) at 204:12–16 (agreeing that "there are all kinds of circumstances when an order can be of unusual size, pattern or frequency, but not be diverted"); 5/25 Tr. (Oriente) at 47:16–18 ("Q. Can you have orders that are of unusual size, pattern of frequency that are legitimate? A. Yes."); Dep. Tr. (Prevoznik) at 1206:6–1209:7 (testifying that there can be "legitimate" reasons for placing orders meeting the regulatory definition of suspicious, including "a new customer base, prescriber, a new doctor's office opened"). In short, because the vast majority of "suspicious orders" are not likely to be diverted, and because McKesson at all times was blocking orders that it determined posed a significant risk of diversion, there is no evidentiary

[14] The testimony of Mr. Rannazzisi is not to the contrary. He acknowledged that he had no direct knowledge about "whether the DEA was aware that it had earlier been standard practice in the industry to file Suspicious Order Reports while continuing to ship product" prior to 2007. *See* 6/9 Tr. (Rannazzisi) at 14:19–15:6.

basis upon which to conclude that McKesson's DEA-approved practice of shipping such orders prior to 2008 caused any diversion or harm in Cabell/Huntington.

Florida "Internet" Pharmacies. Plaintiffs may argue that McKesson made improper shipments to certain Florida-based Internet pharmacies in 2005 and 2006.[15] But there is no evidence that these allegedly improper shipments caused any harm in Cabell/Huntington—let alone that they were a substantial factor in bringing about Plaintiffs' present-day, illegal opioid abuse problem.

In September 2005 and again in January 2006, DEA personnel met with McKesson to discuss its rising concerns that certain DEA-registered pharmacies in Florida were facilitating "Internet pharmacies" that were inappropriately dispensing large quantities of hydrocodone.[16] Within three days of the January meeting, McKesson "terminated all sales of controlled substances to all six pharmacies" identified by the DEA. 6/8 Tr. (Rannazzisi) at 222:10–223:11; *see also* Trial Ex. DEF-WV-01557 at 3. Mr. Rannazzisi acknowledged that the DEA continued to register these pharmacies long after McKesson's terminations, with one pharmacy receiving "close to … 10 million pills after McKesson cut it off during the nine month period where [the pharmacy] remained registered by the DEA." 6/8 Tr. (Rannazzisi) at 227:16–228:4.

As this Court has recognized, evidence of McKesson's distributions to specific pharmacies outside Cabell/Huntington is not relevant unless Plaintiffs establish a "demonstrable nexus" between those distributions and any diversion in Cabell/Huntington. *See* Dkt. No. 1297 at 10. For

[15] The Court may take judicial notice of the fact that the State of Florida has brought its own lawsuit against McKesson. To the extent it is alleged that McKesson improperly distributed prescription opioids to pharmacies in Florida, this lawsuit is not the proper forum for addressing those allegations.

[16] *See* Trial Ex. P-12805 (Memorandum summarizing DEA's September 2005 Internet Presentation with McKesson); Trial Ex. DEF-WV-01549 (Memorandum summarizing January 2006 meeting with McKesson).

several reasons, Plaintiffs' evidence regarding McKesson's distributions to a handful of Florida-based Internet pharmacies in and before early 2006 falls far short of establishing that McKesson was a substantial factor contributing to the present-day opioid abuse problem in Cabell/Huntington.

First, there is no record evidence that any of McKesson's shipments to these out-of-state pharmacies ***ever*** made their way into Cabell/Huntington—let alone caused harm in Cabell/Huntington. Indeed, Mr. Rannazzisi—who was the sole sponsor of the testimony regarding these Internet pharmacies—expressly disavowed having any knowledge relating to distributions or diversion in West Virginia. 6/9 Tr. at 14:6–17 (testifying that he could not identify "any orders in Huntington or Cabell County that [he] believed … should have been blocked" and that he had "not reviewed any documents related to West Virginia."); 6/10 Tr. at 23:8–9 ("I have no knowledge of any distributions into those counties."); *see also* 6/8 Tr. at 216:17–21 ("I'm not aware of any internet pharmacy operating in Huntington or Cabell County"). Accordingly, Plaintiffs have failed to establish a nexus between these out-of-state internet pharmacies and the harms underlying their claim.

Second, in addition to the geographic disconnect, there is also a temporal disconnect between evidence relating to Internet pharmacies and Plaintiffs' public nuisance claim. The record is clear that all Internet pharmacies were shut down by an act of Congress no later than 2008—and that McKesson stopped doing business with these particular pharmacies long before DEA revoked their registrations. Trial Ex. DEF-WV-01557 at 3 ("[A]s of January 9th, 2006, these pharmacies have been terminated by McKesson."); 6/8 Tr. (Rannazzisi) at 223:5–11 (conceding that he "ha[s] no contrary information" suggesting that McKesson distributed to any of the identified pharmacies after January 9, 2006). Especially here, where Plaintiffs have waived any claim for past damages

and seek only the forward-looking remedy of "abatement," *see* Defs.' Abatement Mot. at Part I.A, evidence of isolated, out-of-state conduct occurring more than 15 years ago is plainly insufficient to establish that McKesson is a substantial factor contributing to the present-day opioid crisis in Cabell/Huntington.

Third, any connection between McKesson's alleged wrongdoing in Florida in and before 2006 is too remote and attenuated from the harms underlying Plaintiffs' claims as a matter of law. Before any prescription medicines delivered by McKesson to pharmacies in Florida could reach Cabell/Huntington residents, those medicines would need to be diverted to illicit use, trafficked into Cabell/Huntington, and illicitly used by a Cabell/Huntington resident in the absence of a *bona fide* prescription or legitimate medical need—all of which are criminal acts. As explained in Defendants' Motion for Judgment on Partial Findings Regarding Proximate Causation, where—as here—a defendant's "actions are too attenuated and influenced by too many intervening causes, including the criminal actions of third parties," those actions cannot "stand as the proximate cause of plaintiffs' injuries." *City of Charleston, W. Va. v. Joint Commission*, 473 F. Supp. 3d 596, 631 (S.D. W. Va. 2020).

Generic Hydrocodone Order Monitoring. Plaintiffs may argue that, prior to February 2006, McKesson's systems failed appropriately to identify and monitor orders for generic hydrocodone products. But that argument—supported only by the non-credible, hearsay testimony of Mr. Rannazzisi—is belied by the clear weight of the record evidence. And there is no evidence tying any isolated issues relating to a McKesson distribution facility in Florida in 2006 to Cabell/Huntington's present-day illegal opioid abuse problem.

On direct examination, Mr. Rannazzisi testified that he participated in the January 2006 meeting between McKesson and DEA regarding the Internet pharmacy issue discussed above. In

the course of that testimony, Mr. Rannazzisi speculated that McKesson failed to capture the quantity of hydrocodone distributed to certain Internet pharmacies because its "system to identify suspicious orders" was "not picking up generic drugs in the hydrocodone basic class." *See* 6/8 Tr. at 18:6–18. This speculation was based entirely on McKesson's statement that certain "reports" the company ran "only included the name brand hydrocodone products." Trial Ex. DEF-WV-01549 at 2. But Mr. Rannazzisi did not actually investigate the nature or extent of the issue with those reports; instead he merely posited—incorrectly—that "***chances are***" the issue was widespread. 6/8 Tr. at 18:19–24 (emphasis added). The undisputed record evidence—as well as Mr. Rannazzisi's own testimony on cross-examination—shows that his speculation was incorrect.

Contrary to his testimony, the actual memo that Mr. Rannazzisi referenced makes clear on its face that the DEA calculated McKesson's generic hydrocodone distribution totals to the at-issue Florida pharmacies based on ARCOS data ***provided by McKesson***. *See* DEF-WV-01549 at p. 2 ("The E-Commerce Section retrieved ARCOS data which revealed that … the following alleged Internet pharmacies received the identified quantities of hydrocodone…."). Accordingly, when confronted on cross-examination, Mr. Rannazzisi was forced to admit that McKesson's systems ***were*** capturing and reporting McKesson's generic prescription opioid shipments to DEA:

> Q. And that [information about pharmacy sales] came from the ARCOS data that McKesson reported to the DEA, correct?
>
> A. Yes.
>
> Q. McKesson was reporting both generic data and branded data, correct?
>
> A. Yes.

6/9 Tr. at 61:16–62:6.

Moreover, McKesson's contemporaneous suspicious order reports also showed that McKesson's systems were identifying orders for generic opioid products. *See, e.g.*, MC-WV-

02143. Mr. Rannazzisi thus was again forced to agree that reports to the DEA for McKesson's Lakeland, Florida distribution center—reports which were made "pursuant to the suspicious order regulation"—"covered ***both generic and branded opioids***." 6/9 Tr. at 68:19–22. Indeed, the reports included generic hydrocodone distributions for each of the six pharmacies identified in the DEA's January 2006 memo. *See* MC-WV-02143 at 2, 5, 8, 21, 25, 48; 6/9 Tr. (Rannazzisi) at 63:23–67:16. This contemporaneous record evidence belies Mr. Rannazzisi's claim that McKesson's SOM systems were not "picking up" or reporting generic prescription opioid products to the DEA prior to 2007.

Mr. Rannazzisi further admitted that he had no "information indicating that this was a chronic issue outside of this report at this [Florida] distribution center." *See* 6/8 Tr. at 239:19–22. Accordingly, the Court should not credit Mr. Rannazzisi's baseless assertion of systemic problems relating to McKesson's monitoring of orders for oxycodone and hydrocodone during the pre-February 2006 period.[17]

Finally, there is no evidence that McKesson's Lakeland, Florida distribution center serviced pharmacies in Cabell/Huntington.[18] Accordingly, any isolated issues relating to that distribution center in and before 2006 are too remote—including both temporally and geographically—from Cabell County's present-day illicit opioid abuse problem to support a finding that they were a substantial factor in bringing about Cabell/Huntington's present-day illegal opioid abuse problem.

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[17] Mr. Rannazzisi also testified that he was "sure" that DEA personnel had "check[ed] to make sure" that "McKesson ... immediately fixed [the] reporting issue after they realized it at this [Lakeland] distribution center" in early 2006. 6/8 Tr. at 239:23–240:7.

[18] 5/25 Tr. (Oriente) at 15:15–19 (The "principal distribution center for Huntington and Cabell County" is the "Washington Court House Distribution Center … in Washington Court House, Ohio."); Trial Ex. MC-WV-02149 (Lakeland, Florida distribution center not among the McKesson facilities licensed to distribute to customers in West Virginia).

McKesson's 2008 Settlement. Plaintiffs may argue that McKesson's 2008 settlement with DEA is evidence of wrongdoing on the part of McKesson during this time period, but they would be wrong on both the facts and the law.

McKesson's 2008 settlement agreement does not contain any admission of wrongdoing. To the contrary, the agreement expressly states: "This agreement is neither an admission by McKesson of liability or of any allegations made by the DEA in the Orders and investigation…." P-23733 (2008 Settlement Agreement) at 2. Accordingly, as a matter of black-letter law, this agreement may not be used by Plaintiffs "to prove liability." *Coakley & Williams Const., Inc. v. Structural Concrete Equip., Inc.*, 973 F.2d 349, 353 (4th Cir. 1992) ("[S]ettlement offers are … inadmissible when offered to prove liability or damages."); *see Macsherry v. Sparrows Point, LLC*, 973 F.3d 212, 224 (4th Cir. 2020) (parties are "foreclosed" from using a settlement agreement "to prove the validity of the claim that 'the compromise offer was meant to settle'"); *Wyatt v. Sec. Inn Food & Beverage, Inc.*, 819 F.2d 69, 71 (4th Cir. 1987) ("Fed.R.Evid. 408 … generally forbids testimony regarding compromises or offers to compromise … [that] seek[s] to show the validity or invalidity of the compromised claim."). Indeed, Plaintiffs themselves have acknowledged as much, successfully arguing to the Court that settlement agreements were admissible as providing "notice" and as evidence that "allegations were made," *see* 5/24 Tr. at 83:6–84:14, but ***not*** as evidence that the allegations were true.

In any event, the alleged conduct at issue in that agreement does not relate to McKesson's Washington Courthouse distribution center—which the record shows was the primary McKesson distribution center responsible for servicing Cabell/Huntington during the relevant time-period. 5/25 Tr. (Oriente) at 15:15–19 (identifying the "Washington Court House Distribution Center" as the "principal distribution center for Huntington and Cabell County"); Trial Ex. P-23733 at 1–2.

In light of the geographic and temporal disconnect between the subject matter of the 2008 settlement and Plaintiffs' claims, it is unsurprising that Plaintiffs have failed to come forward with ***any evidence*** tying the alleged conduct at issue in that agreement to any diversion or harm occurring in Cabell/Huntington.

B. McKesson's 2008-13 System Complied with New DEA Guidance Regarding the Shipping of Suspicious Orders and Provided Effective Controls Against Diversion in Cabell/Huntington.

Plaintiffs presented only scant evidence—consisting entirely of Mr. Rafalski's unfounded and inadmissible expert opinions—even purporting to establish any McKesson wrongdoing occurring in or after 2008.[19] And they failed to present any evidence tying that alleged wrongdoing to diversion or harm in Cabell/Huntington—let alone evidence tying that alleged wrongdoing to Cabell/Huntington's present-day, illegal opioid abuse problem.

Beginning in 2007, the DEA announced new, sub-regulatory guidance to distributors.[20] Most notably, this new guidance purported to establish a "do not ship requirement" for orders that distributors identified as potentially suspicious. *See* Trial Ex. P-23736 (72 Fed. Reg. at 36,501); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 222 (D.C. Cir. 2017) ("DEA ***first articulated*** that [do not ship] requirement in *Southwood*…." (emphasis added)); 6/9 Tr. at 46:10–18 (Mr. Rannazzisi confirming that DEA's guidance "was announced in a final order [in

[19] For this reason, if the Court excludes Mr. Rafalski's testimony (and it should), there would be no record evidence of any allegedly actionable conduct by McKesson after 2006.

[20] For the reasons explained in Defendants' Opposition to Plaintiffs' Motion for Partial Summary Judgment Concerning Defendants' Statutory and Regulatory Duties, Dkt. No. 1079, McKesson does not concede that this newly announced, sub-regulatory guidance had the force of law or that any failure to comply with the guidance could constitute actionable conduct.

Southwood], yes, at that point in time"). This new "do not ship" guidance "do[es] not appear anywhere in the statute or in the regulations." 5/26 Tr. (Rafalski) at 255:6–9.[21]

Mr. Rafalski "acknowledged that there was no do not ship requirement before 2007 when [he was] a DEA agent," such that the DEA's new guidance represented a "change in policy." 5/26 Tr. at 252:14–19. Indeed, prior to 2006, Mr. Rafalski could not identify a single distributor that blocked all orders over a threshold. 5/26 Tr. at 269:14-20 ("Q…. [B]efore 2006, is there any distributor you can point me to that blocked every order it reported to the DEA? A. I'm not aware of that, Your Honor.").[22]

McKesson responded to the DEA's changing guidance by adopting a new SOM program, called the Controlled Substance Monitoring Program ("CSMP"), in May 2008.[23] Trial Ex. MC-WV-00381 (2008 CSMP Manual). The 2008 CSMP reflected McKesson's efforts to respond to

[21] During this time-period, DEA also issued new sub-regulatory guidance regarding the use of excessive purchase reports. *See, e.g.*, Trial Ex. P-00034 at 2 (December 2007 letter stating that "reports … indicating 'excessive purchases' do not comply with the requirement to report suspicious orders"); Trial Ex. DEF-WV-03842 at 2 (October 2009 update to the DEA's Diversion Manual adding language stating that "[e]xcessive purchase reports from registrants (reports of unusual sales) **will no longer be accepted** by the DEA" (emphasis in original)); *see also* 6/9 Tr. at 35:11–14 (Mr. Rannazzisi acknowledging that the statement "'Excessive Purchase Reports will no longer be accepted …' doesn't appear" in any prior versions of the DEA manual). By early 2009, McKesson had stopped sending DU-45 reports to the DEA in response to verbal requests to receive fewer suspicious order reports. 5/25 Tr. (Oriente) at 43:1–4 (testifying that McKesson submitted DU-45 reports "up to about 2009"); *id.* at 58:12–15 (testifying to his understanding that, as of late 2008, the DEA "did not want the monthly report of suspicious orders").

[22] Mr. Rannazzisi did not work with distributors prior to 2006 and confirmed he had "no direct knowledge" of the fact "that it had earlier been standard practice in the industry to file suspicious order reports while continuing to ship product." *See* 6/9 Tr. at 14:19–15:6. In September 2006, however, Mr. Rannazzisi wrote a letter in which he proclaimed that "the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion." Trial Ex. P-00033 at 2. Mr. Rannazzisi admitted during his testimony that he could not identify a single distributor that, at the time he wrote this letter praising their compliance efforts, was "blocking suspicious order instead of shipping and reporting." 6/9 Tr. at 17:8–22.

[23] McKesson also operated an interim policy, the Lifestyle Drug Monitoring Program, for a brief eleven month period at "the end of 2007" as "the immediate precursor to the CSMP." 5/25 Tr. (Oriente) at 59:11–60:1. This program "overlapped with Section 55" and did not replace it. *Id.* at 59:11–14; *see also* 5/24 Tr. at 31:7–12 (Oriente) ("Section 55 … I believe, went until 2009.").

the DEA's new expectations, most significantly by designing and implementing a threshold system that "systematic[ally] block[ed]" and did not ship any orders placed by a customer that attempted to order above its threshold. 5/25 Tr. (Oriente) at 62:25–63:3 ("All systematic blocking started in May, 2008."); 6/9 Tr. at 13:18–24 (Mr. Rannazzisi acknowledging that "by 2008 every defendant in this case had a policy in place that involved blocking flagged orders"); Trial Ex. MC-WV-00381 at 6 ("[O]nce a customer has reached their monthly maximum threshold amount, all subsequent orders for that item will be blocked"). As McKesson's Director of Regulatory Affairs, Michael Oriente, testified "McKesson has been systematically blocking orders since 2008," and continues to do so up through the present day. 5/25 Tr. (Oriente) at 9:8–12; *see also id.* 126:2–8 (testifying that with changes to the CSMP in 2013 "[f]ull blocking continued").

Beginning in January 2009, McKesson also adopted a new process for reporting suspicious orders under the CSMP. These changes were made based on McKesson's understanding that the DEA was "getting these large monthly reports … and they did not want to get that much paperwork any longer." 5/25 Tr. (Oriente) at 56:11–19; *id.* at 55:25–56:6 (Mr. Oriente describing that DEA's "feedback was to report less"). Accordingly, under the CSMP, McKesson adopted a process under which "suspicious order designation and reporting" would occur only if an order reached Level III. *Id.* at 80:21–81:6 ("Q. What level would suspicious order designation and reporting occur at? A. At a Level III."); *see also* Trial Ex. MC-WV-00381 at 8 ("Level III Review" instructions indicating that at this stage "[t]he customer / transaction (s) are reported to DEA Headquarters as 'suspicious.'").[24] Because McKesson was "blocking [orders] prior to Level 1 when there's

[24] The CSMP included a three-level review process for threshold changes. *See* Trial Ex. MC-WV-00381 at 7–8. A "Level One" review would occur each time that a pharmacy attempted to place a purchase over a threshold, at which time McKesson "would follow up with that customer and ask why did they attempt to order above their threshold." 5/25 Tr. (Oriente) at 77:12–19. If the Level One review was inconclusive, McKesson would "escalate" to a Level 2 review, which Mr. Oriente

exceeding of the threshold," but "reporting [orders] at Level III," this process resulted in "less suspicious orders reported." 5/25 Tr. (Oriente) at 81:7–15. As Mr. Oriente testified, McKesson understood at this time that "blocking but with less suspicious order reporting" was "what DEA wanted." *Id.* at 81:16–21.[25] Both before, during and after this period, McKesson reported ***all*** of its opioid distributions to DEA through its ARCOS database. 5/25 Tr. at 35:17–36:15 (Mr. Oriente testifying that McKesson's "ARCOS [r]eport[ing] [was] a constant through each of these three time periods" discussed at trial); 5/11 Tr. (McCann) at 143:24–145:2 ("Q. And you found that data that McKesson reported to the DEA into ARCOS and that you relied on from ARCOS to be reliable; correct? A. Correct.").

Alleged Due Diligence Failures. There is no record evidence that the CSMP McKesson put in place in 2008 was not appropriately designed to prevent diversion and identify potentially suspicious orders. While Plaintiffs vaguely suggest that McKesson operated the program in a deficient manner, the sole basis for that suggestion was Mr. Rafalski's ***assumption*** that McKesson failed to conduct adequate diligence on its customers. The overwhelming weight of the factual evidence in the record conclusively disproves that assumption.

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described as requiring him "or one of [his] counterparts … to do a review of that pharmacy." *Id.* at 78:12–19. If the Director of Regulatory Affairs conducting a Level Two review was not satisfied with the pharmacy's explanation, "[t]hen it would be escalated to … senior management" as part of a Level III review, at which time "all controlled substances for that customer, not just that specific base code that was blocked, would be blocked." *Id.* at 79:9–18.

[25] McKesson made multiple presentations to the DEA during which it outlined the operation of CSMP. At one meeting in November 2008, Mr. Oriente expressly told "DEA that there would be orders that would be blocked but not reported as suspicious because they didn't make it to Level III," with DEA indicating no disagreement. 5/25 Tr. at 110:2–8; Trial Ex. P-42657 at 16 (Presentation to DEA indicating that "Level 3 Review … Reported to DEA as suspicious."); *see also* Trial Ex. MC-WV-00397 at 12 (July 2008 presentation to DEA conducted by McKesson Senior Vice President of Distribution Operations, Donald Walker, informing DEA that orders are "[r]eported to DEA as suspicious" only upon escalation to a "Level III Review").

McKesson's CSMP system set thresholds based on customer-specific due diligence that sought to understand each customer's business model and distribution needs. 5/25 Tr. (Oriente) at 24:23–25:13 (Mr. Oriente testifying that thresholds cannot be set with a "one size fits all approach"). McKesson could modify these customer-specific thresholds based on a threshold change request ("TCR") form, completed by the customer, that explained the basis for its requested threshold increase—but only after the TCR was reviewed by and received approval from a Director of Regulatory Affairs. 5/25 Tr. (Oriente) at 75:18–22.

Over more than six weeks of testimony, the only witness who even arguably attempted to call into question the sufficiency of McKesson's post-2007 systems was Mr. Rafalski.[26] McKesson respectfully submits that Mr. Rafalski's testimony—and in particular his *ipse dixit* opinions that Defendants failed to operate "effective" SOM systems—should be excluded. *See* Dkt. Nos. 1385, 1398, 1405, 1418. But even if the Court admits the testimony, it is neither credible nor sufficient to overcome the clear weight of the record evidence.

At no point during his testimony did Mr. Rafalski opine that the thresholds used by McKesson under the CSMP were set too high. Indeed, there is ***no record evidence that McKesson's thresholds***—including for any customers in Cabell/Huntington—***were set inappropriately***. Mr. Rafalski, moreover, acknowledged that McKesson did not ship any orders that exceeded the thresholds it set. 5/26 Tr. at 207:2–6 (agreeing that "since 2007 and 2008, … McKesson ha[s] blocked orders that go above specific thresholds"). Nor did Mr. Rafalski ever

[26] Plaintiffs attempted to ask Mr. Rannazzisi a limited number of questions about McKesson's post-2006 conduct, but Mr. Rannazzisi had no recollection—and offered no concrete, non-conclusory testimony—regarding any interactions he had with McKesson after the 2006 time-period. *See, e.g.*, 6/10 Tr. at 69:25–70:5 ("I don't recall. I don't recall that being relayed to me in 2007."); *id.* at 71:4–6 ("If you're asking me do I recall the specifics of this meeting, no…."); *see also id.* at 86:21–25 (acknowledging that he had "never seen this document before Plaintiffs' lawyer show it to [him] after he left the DEA").

identify any other specific feature of the CSMP's design that he believed was in any way deficient. Accordingly, there is no record evidence that McKesson failed to design an effective system for preventing diversion.

While Plaintiffs suggest that McKesson failed to conduct appropriate diligence before approving threshold increases under the CSMP, relying on the testimony of Mr. Rafalski, that testimony makes clear that Mr. Rafalski merely ***assumed*** no due diligence was done. He admitted that he did not review "***any*** of the orders flagged by [his] methodologies," including any of the "initial triggers," before making his no-due-diligence assumption, 5/26 Tr. at 214:13–215:6:

> Q…. Have you looked at those initial orders for McKesson … that are the initial flagged orders of your Method A?
>
> A. I have not, Your Honor.
>
> Q. Did you individually review any of them to see if you just looked at the order on its face whether you would consider it to be suspicious?
>
> A. I did not, Your Honor.

5/26 Tr. at 227:20–228:3. Nor did he review the "diligence files" for each of the "flagged orders" or "look[] at which pharmacies generate the most flagged orders" before employing his assumption. 5/26 Tr. at 215:8–10, 228:4–11. Rather, he merely "***assum***[***ed***]" that no diligence was done. *See, e.g.*, 5/26 Tr. at 227:1–9.

In opposing Defendants' motion to exclude Mr. Rafalski's testimony, Plaintiffs attempted to back-fill that assumption by pointing to Mr. Rafalski's subsequent partial reviews of Defendants' document productions. But, as described above, Mr. Rafalski admitted that he did not review all of the diligence files or any of the flagged orders. And while Plaintiffs attempted to justify the assumption by asserting that the "absence of documentation means an absence of due diligence," Dkt. No. 1396 at 11, that lawyer argument was contradicted by Mr. Rafalski's own

sworn testimony. Mr. Rafalski admitted that the absence of more complete documentation in Defendants' litigation productions is ***not*** necessarily an indication that proper diligence was not done at the time the orders were placed. Specifically, Mr. Rafalski admitted that:

- he does not know, of his flagged orders, how many were "actually investigated and the flag cleared by the defendants," 5/26 Tr. at 228:21–229:6;
- no regulation requires wholesale distributors to retain diligence files—many of which would be decades old, 5/26 Tr. at 269:21–25; and
- older documents may not have been produced in this litigation merely because they "weren't kept" by Defendants up through the time that litigation commenced, 5/27 Tr. at 12:23–13:6.

Accordingly, Mr. Rafalski simply does not have the knowledge—and has not done the work—that would be needed to justify his assumption that McKesson failed to conduct adequate due diligence on its customers.[27]

This is especially clear in light of the fact that Mr. Rafalski's assumption is contradicted by the entirety of the factual testimony that Plaintiffs elicited over the past seven weeks. McKesson's CSMP included diligence conducted when customers were first "onboarded."[28]

[27] Plaintiffs' argument that *Masters* supports the inference from an absence of diligence files to an absence of diligence, Dkt. No. 1396 at 12, is misplaced. While the absence of a *contemporaneous* business record may be some evidence that a transaction did not take place, the absence of more complete files *decades after* the events in question took place would not—especially where, as here, there was no obligation to retain those records. *See* 5/26 Tr. at 269:21–270:14; *see also* 5/25 (Oriente) at 43:5–10 ("Do you know of any policy at McKesson that DU45s had to be kept over a 10-, 15-, 20-year period every time they were reported? A. No. The retention period would have been two years."); *id.* at 76:6–9 ("Q. If we try to find diligence for a given pharmacy today and we can't find a file, does that mean it was never conducted? A. No, it wouldn't.").

[28] *See* Trial Ex. MC-WV–00381 at 9 (CSMP manual with "New Customer On-Boarding Process"); Trial Ex. MC-WV-00185 (new customer questionnaire). As part of the onboarding process, McKesson would "go visit that pharmacy, see the physical location of it, make sure that … they're licensed by the state and that they also have a DEA registration … [and] also have the new customer start-up fill out a questionnaire." 5/25 Tr. (Oriente) at 83:3–16; Trial Ex. MC-WV-00185 (Independent, Small, Medium Chain Customer Questionnaire). And if a pharmacy had previously done business with another distributor, McKesson would "ask for dispensing information in order to review where threshold should be set and also to identify what it was that they were dispensing."

McKesson also conducted ongoing due diligence of existing customers, including site visits and evaluations of dispensing data.[29] Indeed, Plaintiffs have introduced examples of McKesson's due diligence into the record that belies Mr. Rafalski's assertion that no records of diligence exist. *See, e.g.*, Trial Ex. P-13284 (diligence materials for Custom Script pharmacy, including Level I forms, a completed customer questionnaire, pictures taken during a visit to the pharmacy, and notes from a visit by Director of Regulatory Affairs).

In addition, when a customer attempted to order over their threshold, that customer could request a threshold change. In order to evaluate such a request, McKesson would require a TCR form filled out by the customer explaining "why do they need the increase," and well as "dispensing data on that particular base code [the active ingredient for which a request was being made to increase the threshold] so we could see their dispensing patterns." 5/25 Tr. (Oriente) at 75:5–17. All TCRs had to be approved by "one of the four [regional Directors of Regulatory Affairs]" based on a demonstrated need for an increase before a customer's threshold could be adjusted. *Id.* at 75:18–22; *see also id.* at 163:15–165:1 (confirming that he "regularly reinforced" the expectation that threshold change requests provide detailed information and explain the reasons for a change).

5/25 Tr. (Oriente) at 83:17–24. Based on the diligence conducted during this onboarding process, "there were times when we refused a customer from coming to McKesson." *Id.* at 90:10–14.

[29] McKesson's onboarding procedures were only the "start of the diligence" it conducted on its customers. 5/25 Tr. (Oriente) at 90:15–17. For example, Mr. Oriente testified to "go[ing] out and visit[ing] pharmacies" on a weekly basis, focused on ensuring that he visited "pharmacies that were the highest purchasers of [prescription] opioid drugs," as well as pharmacies that frequently attempted to order above a threshold or made "frequent requests for [threshold] increases." *Id.* at 91:23–92:19. During site visits, McKesson's regulatory affairs employees would look for potential "red flags" such as "out-of-state plates," whether the store was a "full-service pharmacy" that offered over-the-counter goods and medical supplies, and what percentage of customers were "paying with cash." *Id.* at 93:22–94:17.

In sum, any suggestion that McKesson failed to conduct adequate diligence on its customers under the CSMP is belied by the overwhelming weight of the record evidence. Mr. Rafalski's unsupported, *ipse dixit* opinion that this system nonetheless was deficient is contrary to the record and should be rejected. McKesson is therefore entitled to judgment under Rule 52(c). *See, e.g.*, Wright & Miller, Federal Practice and Procedure, § 2573.1 ("The court's task [in deciding a Rule 52(c) motion] is to weigh the evidence, resolve any conflicts in it, and decide for itself in which party's favor the preponderance of the evidence lies.").

In any event, even assuming *arguendo* that McKesson operated its CSMP program in a deficient manner, that alone could not save Plaintiffs' claims. Rather, Plaintiffs would also need to prove that those alleged deficiencies led to diversion in Cabell/Huntington. As explained above, there is ***zero evidence*** of diversion occurring at any of McKesson's handful of retail pharmacy customers in Cabell/Huntington. *See supra* Part I.C. Rather, the undisputed record evidence shows that (i) any diversion that occurred took place after McKesson delivered prescription opioid medicines to its DEA-registered pharmacy customers in Cabell/Huntington, and (ii) McKesson has no duty, and no ability, to prevent that "medicine cabinet" diversion. *See* Defs.' Proximate Causation Mot. at Part I.B.1. Accordingly, McKesson is entitled to judgment under Rule 52(c) irrespective of whether the Court concludes that the CSMP program was designed or operated in a deficient manner.

2017 Settlement Agreement. Plaintiffs may point to McKesson's 2017 settlement with the DEA as evidence of wrongdoing during the post-2007 time-period, but they would be mistaken.

As an initial matter, it is black-letter law that settlement agreements are not admissible to prove that a settling defendant actually engaged in the conduct alleged by the plaintiff (in this case, the DEA). *See supra* at 25–26. While the 2017 agreement contains a limited "acceptance of

responsibility" provision, that provision does not change the fact that the agreement cannot be used as a basis for concluding that McKesson's alleged conduct led to any diversion or harm in Cabell/Huntington.

The relevant provision states:

> McKesson acknowledges that, at various times during the … Covered Time Period … it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters[30] about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

P-00013 at ¶ I.2. Notably, there is no admission in the agreement that McKesson ever shipped a "suspicious order" or an order that McKesson knew or should have known was likely to be diverted. *Id.* Instead, the sole admission relates to the ***reporting*** of suspicious orders to DEA. *Id.*; *see* 6/10 Tr. (Rannazzisi) at 87:14–16 (agreeing that the settlement includes "no language in there about failing to block"). The record evidence leaves no doubt that these reporting shortcomings could not possibly have led to diversion in Cabell/Huntington.

As an initial matter, there is no evidence that any of the orders that McKesson allegedly failed to report were placed by any of McKesson's small number of pharmacy customers in Cabell/Huntington. *See, e.g.*, 6/10 Tr. at 87:1–16 (Mr. Rannazzisi admitting that he did not know "if any of those orders or pharmacies [identified in the narrow of "acceptance of responsibility"

[30] The agreement defines the "DEA Letters" as the three letters sent by Joseph Rannazzisi to the wholesale distribution industry in 2006 and 2007. *See* P-00013 at ¶ I.2. For the reasons explained in Defendants' Opposition to Plaintiffs' Motion for Partial Summary Judgment Concerning Defendants' Statutory and Regulatory Duties, Dkt. No. 1079, McKesson disputes that these letters have any binding effect, and therefore that any failure to follow "guidance" in those letters that exceeded the scope of the applicable regulations violated the law or was in any way wrongful.

provision] are in Huntington-Cabell"). Absent such evidence, McKesson's alleged reporting failures are irrelevant to this case.

More fundamentally, as Plaintiffs' own diversion expert admits, "not reporting the suspicious order to the DEA ***is not what causes diversion***." 5/26 Tr. (Rafalski) at 208:10–12 (emphasis added). The period covered by the 2017 agreement begins on January l, 2009. As described above, McKesson implemented its CSMP no later than May 2008. The undisputed record evidence shows that ***McKesson blocked and did not ship any suspicious orders beginning in 2008***, when the CSMP went into effect. 6/9 Tr. at 13:18–24 (Mr. Rannazzisi agreeing that "by 2008 every defendant in this case had a policy in place that involved blocking flagged orders"); 5/25 Tr. at 55:12–17 (Mr. Oriente confirming that McKesson "starting blocking all orders that exceeded threshold[s]" as of 2008). And, as Plaintiffs' own witnesses—including Mr. Rannazzisi and Mr. Rafalski—admit, ***an order that is not shipped cannot be diverted or cause any harm***. *See* 5/26 Tr. at 208:7–9 (Mr. Rafalski agreeing that blocking an order is "what prevents diversion from occurring"); 6/9 Tr. at 13:25–14:5 (Mr. Rannazzisi acknowledging that a blocked order "can't go downstream" and therefore "can't be diverted"). Accordingly, the orders that McKesson allegedly failed to report, by definition, could not have been diverted into Cabell/Huntington, and so could not have been a "substantial factor" in bringing about the alleged public nuisance in Cabell/Huntington. For this additional reason, the 2017 settlement agreement cannot save Plaintiffs' claim against McKesson from judgment pursuant to Rule 52(c).

C. Plaintiffs Failed To Offer Any Evidence of Any Deficiency in McKesson's Post-2012 System.

Plaintiffs failed to present ***any concrete evidence*** of any deficiencies in McKesson's post-2012 SOM program or any evidence of diversion or harm occurring in Cabell/Huntington as a result of any McKesson conduct in or after 2013.

McKesson continued its three-level reporting process until 2013, when—based on new DEA guidance—it made "further changes to its processes" resulting in more "frequent" suspicious order reporting. 5/25 Tr. (Oriente) at 125:13–25. For the last eight years, McKesson has continued to block all orders in excess of a threshold, and has also reported ***all*** blocked orders to the DEA as suspicious. *Id.* at 125:23–126:8 (Mr. Oriente testifying that starting in 2013 "[f]ull blocking continued" and reporting became "frequent and involved all suspicious orders"). There is no concrete evidence of any reporting failures during this time-period.

McKesson also made additional enhancements to its CSMP in 2013, including "more sophisticated data analysis, [a] more rigorous process for threshold change requests" and the expansion of the regulatory affairs team to include individuals with "experience as DEA diversion investigators." 5/25 Tr. (Oriente) at 129:3–24; *see also* Trial Ex. MC-WV-00199 (McKesson's 2015 CSMP Manual) at 6 (identifying expanded Regulatory Affairs team of approximately 25 individuals).[31]

Plaintiffs have offered no critiques of McKesson's current CSMP processes, and have focused their evidence almost entirely on the pre-2013 time period. *See* 5/14 Tr. at 10:6–10 (Plaintiffs' counsel stating that "eliciting testimony about current customers or current [SOM] programs, we fail to see how it has anything to do with the flood of pills that were sold into West Virginia, into this community, giving rise to the opioid epidemic"); 5/24 Tr. (Oriente) at 225:20–23 (Plaintiffs asking questions about alleged shortcomings in suspicious order reporting from "May, 2008" through "July, 2013"). Indeed, far from criticizing the operations of McKesson's

[31] Additionally, beginning in 2015, McKesson hired an outside consulting firm, Analysis Group, Inc., to develop an algorithm that automatically sets monthly threshold by taking "into account the specific customer, but also tak[ing] into account the geographic area, as well as looking at sort of a rating scale of the most abused [drug] base codes." 5/25 Tr. (Oriente) at 136:7–23.

post-2013 SOM program, Plaintiffs have positively highlighted aspects of the McKesson program as it has been designed and operated for the past eight years.[32]

CONCLUSION

For the foregoing reasons, Plaintiffs have failed to prove that McKesson engaged in any actionable conduct that was a substantial factor in bringing about the alleged public nuisance, and so McKesson is entitled to judgment on partial findings under Rule 52(c).

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Respectfully Submitted,

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[32] *See, e.g.*, 5/24 Tr. (Oriente) at 135:2–13 (Plaintiffs' counsel highlighting a "threshold reduction effort" conducted by McKesson in 2013 and 2015); *id.* at 149:3–19 (Plaintiffs' questioning highlighting that in 2013 McKesson was "in the process of implementing an enhanced suspicious order monitoring program"); *id.* at 150:14–17 (Plaintiffs' counsel emphasizing changes to McKesson's process for reviewing threshold change requests).

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 1st day of July, 2021, the foregoing "MEMORANDUM OF LAW IN SUPPORT OF MCKESSON'S MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING ACTIONABLE CONDUCT" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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